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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,466

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Gary S. Dixon

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EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/623,466

Applicant(s)

DIXON ET AL.

Examiner

Jacqueline Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 44-47 is/are allowed.
- 6) ☐ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-34 and 44-47 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 5-8, 12-15, 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang (US 2003/0015208 A1).
4. **Claims 1, 5-8, 12-14, 23, 24, 33, 34:** Lang discloses a method of diagnosing bone related diseases where using a combination of several independent measurements or tests provides for greater diagnostic power. Information provided by imaging tests along with information provided by biomarkers are used to assess the disease and determine a treatment (paragraphs 0014, 0015, 0030, 0031). The imaging test can include imaging systems such as ultrasound, X-ray, and CT and the tests that obtain information from these images can be values such as such as bone mineral density or a movement pattern of the joint (gait analysis) (paragraphs 0027, 0033, 0034, 0047). The biomarkers of a bone marker concentration can be taken from a body fluid such as urine to identify bone resorption levels (paragraphs 0026). Depending on the results of the

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combination of these tests a treatment is prescribed (paragraphs 0069, 0072). Lang does not specifically disclose an order of the tests, but the examiner respectfully disagrees with the applicant's argument that the "applicant's claim recognize that the test order *does* make a difference and further, proposes a specific protocol for ordering the diagnostic tests" because the applicant claims in claim 33 that the "steps of measuring a bone characteristic level, conducting a gait analysis and measuring a bone marker concentration *may be performed in any order*" showing that the test order does not make a difference. Therefore the examiner believes that Lang could perform the tests in any order of which the order is capable of being first the bone characteristic level, then the gait analysis, and then finally the bone marker concentration. Also currently Lang does do each of the tests based upon the value of the scores. It would be obvious to one skilled in the art that to mathematically combine the information provided by the tests a value must be outputted from each of the tests, before the next test would be performed.

5. **Claim 15:** Lang teaches measuring a bone marker level. It is inherent that to measure the bone marker level in a body fluid such urine the body fluid must be put in a container to be analyzed and to obtain the bone marker level a output must be outputted. Since the result would be the same whether there is a mechanism for holding the container with the sample, or if the container of the sample itself was analyzed without the extra mechanism, the mechanism has no criticality.

6. **Claims 21, 22, 25-32:** Lang teaches that the biomarkers and the imaging descriptors can be measured over a period of time, which can be seconds, minutes, hours, days, or months, or any interval there between (paragraph 0067).

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7. **Claims 2-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang as applied to claim 1 above, and further in view of Chaintreuil (US 6,234,969 B1). Chaintreuil discloses a bone densitometer having a housing for a foot in which a pair of ultrasonic transducers engages the heel at a controlled pressure. The ultrasonic waves that are detected are the used to calculate an quantitative ultrasound index, or a stiffness value (fig. 1, col. 4 line 14-61). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Chaintreuil with Lang as Lang discloses using ultrasound measurements for the imaging test.

8. **Claims 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang as applied to claim 1 above, and further in view of Faulkner (US 6,740,041 B2). Faulkner et al. discloses a bone densitometer that accepts additional patient data to produce a more accurate output measurement of a person's risk of osteoporosis. Bone densitometers provide a measurement of a bone characteristic level such as the T-score of a bone mineral density. These measurements are typically taken with x-ray, ultrasound, or tomography (col. 1 line 6-50). The bone densitometer of Faulkner et al., takes into account the risk factors of a patient such as the age of the patient and the patient's history of fractures when determining the patients' risk of fracture. This information is inputted into a computer, which processes and displays the information (col. 2 line 66-col. 3 line 5). It would be obvious to one skilled in the art to combine Faulkner with Lang as Lang discloses that the imaging test includes (but is not limited to) broadband ultrasound attenuation so the result from the bone densitometer test of Faulkner can be an imaging test as disclosed in Lang. The result of Faulkner has risk factors attributable to a patient embedded in the result.

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9. **Claims 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang as applied to claim 1 above, and further in view of Pratt (US 4,195,643). Although Lang does not disclose using a gait analysis system as claimed, he does disclose that using a gait analysis such as studying the movement of the joint is a helpful diagnosis for bone disease. It would therefore be obvious to one skilled in the art to use any well known measuring and characterizing of gait to help make an even better determination of a bone related condition. Pratt discloses such a well known apparatus for characterizing gait of a subject. In his system, to measure and characterize the gait, a person stands on a dual force plate system, which determines the force exerted by the right foot and the left foot. These forces can be compared to determine a difference in the forces exerted by each foot, and determine balance forces of the subject (col. 5 line 61-col. 6 line 14, fig. 3). Balance forces of a subject can also be measured with one foot off the ground (col. 9 line 62-65). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Pratt with Lang as Lang discloses that analyzing gaits helps to detect the deterioration of bones.

10. **Claims 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang as applied to claim 1 above, and further in view of Uitterlinden (US 6,803,197 B1). Uitterlinden discloses therapy for treatment of osteoporosis can include modifications to lifestyle, regular exercise, hormone therapy, bisphosphonates, vitamin D and calcium supplements. Since these are well known in the art that it would be obvious that these therapies would be recommended for a patient. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Uitterlinden with Lang as these are well know ways to treat osteoporosis.

Allowable Subject Matter

11. Claims 44-47 are allowed.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC


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SUPERVISORY PATENT EXAMINER